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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,960	11/21/2000	Michael Brines	10165-009-999	6595

20583 7590 05/08/2006

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222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,960	Applicant(s) BRINES ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,9,11-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9,11,15 and 17-23 is/are rejected.
- 7) ☒ Claim(s) 12-14 and 24-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The finality of the rejection of the last Office Action is *withdrawn* in view of the new grounds of rejection set forth below.

Status of Application, Amendments and/or Claims

The amendment filed 19 July 2005 has been entered in full. Claims 7, 10, 16 and 27 are cancelled. Claims 1-6, 8, 9, 11-15, 17-26 are pending and under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection to claims 15-27 under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 2-5 of the previous Office Action (19 January 2005) is *withdrawn* in view of the amendment (19 July 2005).

Claim Rejections - 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8, 9, 11, 15, 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman *et al.*, American Journal of Kidney Disease, July 26(1):202-

8 (1995). The instant claims are drawn to a method for protection of an excitable tissue in a mammal having a neurodegenerative condition, comprising administering peripherally to a mammal in need thereof an effective non-toxic amount of EPO for the protection of an excitable tissue. The instant claims are also drawn to a method for protection of an excitable tissue in a mammal having...diabetic neuropathy or hypoxia.. comprising administering peripherally to a mammal in need thereof an effective non-toxic amount of EPO for the protection of an excitable tissue. The instant specification teaches excitable tissue as neuronal and heart tissue (page 1, line 14).

Friedman *et al.* teach the intravenous and subcutaneous administration of recombinant EPO to diabetic patients (with anemia attributed to renal insufficiency) and subsequent eye evaluations (i.e. prior to medical procedure) (Patients and Methods, page 202-203). Friedman *et al.* teach improvement in macular edema. Friedman *et al.* discusses the pathogenesis of diabetic complications. Friedman *et al.* cite references that state hypoxia contributes to resistance to ischemic conduction failure, which is a characteristic of diabetic neuropathy. Friedman *et al.* teach that hyperbaric oxygenation was shown to partially reverse the neuropathy in diabetic-induced rats (page 206, last paragraph). Friedman *et al.* teach that raising red cell mass by treating with EPO should increase retinal oxygenation (page 206, Figure 4). Friedman *et al.* teach a correlation between EPO administration, tissue oxygenation and neuropathy treatment (page 206, Figure 5). Lastly, Friedman *et al.* teach that in azotemic diabetic patients, EPO is well tolerated without major complications. Friedman *et al.* teach that extension of the application of EPO to azotemic patients who do not require dialytic therapy expanded

the indication for this hormone replacement. Friedman *et al.* teach that fear that a higher hematocrit and associated raised blood viscosity might accelerate the rate of decline of renal function in azotemic patients has been assuaged and that their reports is consistent with prior reports documenting the absence of cerebrovascular or cardiovascular complications precipitated by EPO-induced increased blood mass (page 205).

It would have been obvious to one of skill in the art at the time the invention was made to modify the method of Friedman *et al.* by using it to protect excitable tissue in a mammal having a neurodegenerative condition or protection of excitable tissue in a mammal having diabetic neuropathy comprising administering EPO with a reasonable expectation of success. The motivation and expected success is provided by Friedman *et al.*, who teach that hyperbaric oxygenation was been shown to partially reverse the neuropathy in diabetic-induced rats (diabetic neuropathy, neurodegenerative condition). Friedman *et al.* teach that EPO increases retinal oxygenation and that upon EPO administration, diabetic retinopathy was improved. Friedman *et al.* teach a correlation between EPO administration, tissue oxygenation and neuropathy treatment (page 206, Figure 5). Friedman *et al.* also teach EPO is well tolerated without major complications.

Claim Objections

Claims 12-14 and 24-26 are objected to for depending from a rejected claim.

Conclusion

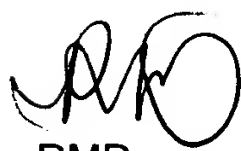
Claims 1-6, 8, 9, 11, 15, 17-23 are rejected.

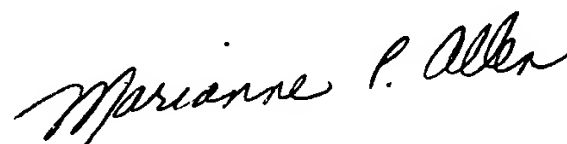
Claims 12-14 and 24-26 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RMD
5/2/06


MARIANNE P. ALLEN
PRIMARY EXAMINER
5/4/06
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